IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CAROLINE IDELUCA,

Plaintiff,

v.

C.R. BARD, INC., DAVOL, INC.,

Defendants.

17cv1355
ELECTRONICALLY FILED

MEMORANDUM ORDER

Recently, this Court issued an Opinion in *Stevens v. C.R. Bard et al*., 2:17-cv-1388, denying Defendants' Motion to Dismiss negligence and breach of warranty claims. After this Court issued it Opinion in *Stevens*, Defendants herein withdrew their argument suggesting Plaintiffs' negligence claims in the immediate case should be dismissed.

However, Defendants renewed their Motion to Dismiss Plaintiff's product liability claim in the instant matter. Specifically, Defendants seek to dismiss Count I of Plaintiff's Complaint which asserts a claim for strict liability against a product identified as "Marlex Mesh," which is hernia mesh made from polypropylene. (In *Stevens*, the plaintiff did not assert a strict liability claim.)

I. STANDARD OF REVIEW

In considering a Rule 12(b)(6) motion, Federal Courts require notice pleading, as opposed to the heightened standard of fact pleading. Fed. R. Civ. P. 8(a)(2) requires only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds on which it rests.'" *Bell*

Atlantic Corp. v. Twombly, 550 U.S. 554, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Building upon the landmark United States Supreme Court decisions in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Court of Appeals for the Third Circuit explained that a District Court must undertake the following three steps to determine the sufficiency of a complaint:

> First, the court must take note of the elements a plaintiff must plead to state a claim. Second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. Finally, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.

Connelly v. Steel Valley Sch. Dist., 706 F.3d 209, 212 (3d Cir. 2013) (citation omitted).

The third step requires this Court to consider the specific nature of the claims presented and to determine whether the facts pled to substantiate the claims are sufficient to show a "plausible claim for relief." *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013). "While legal conclusions can provide the framework of a Complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 664.

This Court may not dismiss a Complaint merely because it appears unlikely or improbable that Plaintiff can prove the facts alleged or will ultimately prevail on the merits. *Twombly*, 550 U.S. at 563 n.8. Instead, this Court must ask whether the facts alleged raise a reasonable expectation that discovery will reveal evidence of the necessary elements. *Id.* at 556. Generally speaking, a Complaint that provides adequate facts to establish "how, when, and where" will survive a Motion to Dismiss. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 212 (3d Cir. 2009).

In short, a Motion to Dismiss should not be granted if a party alleges facts, which could, if established at trial, entitle him/her to relief. *Twombly*, 550 U.S. at 563 n.8.

II. DISCUSSION

Pennsylvania law requires that a plaintiff prove two elements in a strict product liability action: (1) that the product was defective, and (2) that the defect was a substantial factor in causing the injury. *See Spino v. John S. Tilley Ladder Co.*, 696 A.2d 1169, 1172 (Pa. 1997). There are three different defective conditions which give rise to a strict liability claim in Pennsylvania: (1) design defect, (2) manufacturing defect, and (3) failure-to-warn defect. *Phillips v. A–Best Products Co.*, 542 Pa. 124, 665 A.2d 1167, 1170 (1995).

Defendants claim that because the product is a medical device, Plaintiff cannot assert a claim for strict liability.[1] In support of their position Defendants contend that Section 402A of the Restatement (Second of Torts) -- which was adopted by the Supreme Court of Pennsylvania in *Webb v. Zern*, 220 A.2d 853 (Pa. 1966) -- controls this matter. Specifically, Defendants rely upon the application of Comment K to Section 402A, which reads:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because

[1] Plaintiff labelled the mesh at issue in this case "a medical device" (see paragraph 7 of the Complaint), and this Court accepts that label as true.

> of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A (1965).

Pennsylvania's Supreme Court adopted Comment K with respect to prescription medication. In *Hahn v. Richter*, the Pennsylvania Supreme Court recognized that comment K specifically applied to prescription drugs. *Hahn*, 673 A.2d 888, 889-90 (Pa.1996) ("Comment K . . . denies application of strict liability to products such as prescription drugs, which although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.").

In this case, Defendants argue that Comment K stretches beyond prescription medications and applies to cases involving medical devices. Defendants rely upon numerous cases originating from the United States District Court for the Eastern and Western Districts of Pennsylvania in support of this contention. *See, i.e., Parkinson v. Guidant Corp*., 315 741 (W.D. Pa. 2004) ("While it is true that no Pennsylvania court expressly has applied comment K to prescription medical devices, numerous courts in the Eastern District of Pennsylvania, applying Pennsylvania law, have predicted that the Pennsylvania Supreme Court will extend comment K to such devices."), *citing Taylor v. Danek Medical, Inc.*, 1998 WL 962062 (E.D. Pa. 1998) (The Pennsylvania Supreme Court, pursuant to its reasoning in *Hahn*, where it recognized that prescription drugs present a unique set of risks and benefits in that what may be harmful to one patient may be beneficial to another, will determine that prescription medical devices likewise

are not covered by Section 402A because they present the same "unique set of risks and benefits" as prescription drugs.).

Plaintiff, however, contends she has asserted a meritorious and legally cognizable strict liability claim for a manufacturing defect which should not be dismissed. *See Dougherty v. C.R. Bard, Inc*., 2012 WL 2940727 (E.D. Pa. 2012) (The Pennsylvania Superior Court read *Hahn* and its predecessors more narrowly and recognized a strict-liability claim based on an alleged manufacturing defect as a viable cause of action against a manufacturer of prescription drugs.). *See also Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. 2010) ("As noted above, Appellant did not allege that Redux contained a manufacturing defect or inadequate warnings. The trial court, therefore, did not err in granting summary judgment in favor of Wyeth on Appellant's 'Unreasonable Marketing' claim to the extent that it averred a strict liability design defect claim.") In addition, *see Killen v. Stryker Corp*., 212 WL 4498865 (W.D. Pa. 2012), and *Wagner v. Kimberly Clark Corp*., 225 F. Supp 3d 311 (E.D. Pa. 2016). In each of these federal cases, the deciding court determined either expressly or impliedly that Pennsylvania law does <u>not</u> preclude a strict lability claim based upon a manufacturing defect.

This Court concludes as follows based on the foregoing law and analysis: Comment K to Restatement (Second) of Torts, Section 402 A, precludes a cause of action in strict liability against a prescription drug manufacturer – depending on the basis of the strict liability claim. Next, the United States District Courts for the Eastern and Western Districts of Pennsylvania have not decided with unanimity whether comment K also applies to preclude strict liability claims against medical device manufactures when such a claim arises out of a manufacturing defect. Third, Pennsylvania's Supreme Court has not yet taken a position on whether a plaintiff may sue a medical device manufacturer for strict product liability arising from

a manufacturing defect. Finally, Pennsylvania's Superior Court, most recently in *Lance*, suggests that not all forms of strict product liability claims are forbidden.

For these reasons, the Court will deny Defendant's Motion to Dismiss Count I of the Plaintiff's Complaint which adequately pleads a claim for strict product liability arising out of a manufacturing defect with respect to the medical device ("Marlex Mesh") at issue in this case. As noted above, Defendants withdrew the portions of their Motion with respect to Plaintiff's negligence claims. Thus, all claims asserted in Plaintiff's Complaint will proceed.

ORDER OF COURT

AND NOW this 9th day of February, 2018, after having carefully considered the arguments set forth by Defendants and Plaintiff, the Court hereby DENIES the Defendants' Amended Motion to Dismiss (doc. no. 19), requesting that Count I of Plaintiff's Complaint be dismissed. Defendants' Answer to Plaintiff's Complaint is due on or before February 22, 2018.

s/ Arthur J. Schwab
Arthur J. Schwab
United States District Judge

cc: All ECF Registered Counsel of Record